Remarks

The following is in response to the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures, mailed April 17, 2002, in the above-identified application. Applicants' authorization, in the accompanying Transmittal Letter, to charge Deposit Account 01-0025 in the amount necessary to cover the cost of any fee due under 37 CFR 1.16 or 1.17 constitutes a constructive petition for an extension of time. Accordingly, this response is filed timely.

In response to the Notice, Applicants submit herewith:

(1) an initial paper copy of the Sequence Listing;

(2) an initial computer readable form copy of the Sequence Listing; and

(3) a statement to support the filings and submissions in accordance with 37 CFR §§1.821-1.825. Applicants also provide an amendment directing the placement of the paper copy of the Sequence Listing into the specification.

Applicants also have amended the specification to identify each sequence with its appropriate sequence identifier (SEQ ID NO:). A marked up version of the specification, showing the amendments made, is included herewith as ATTACHMENT A.

Applicants respectfully submit that the amendments add no new matter and request their entry into the record.

Respectfully submitted,
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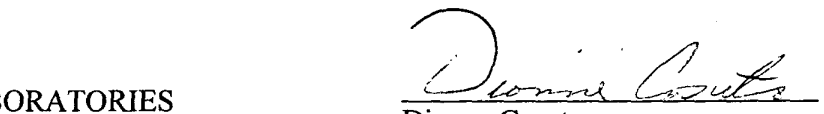

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ATTACHMENT A
(Marked up version showing changes made)

Marked up version of the paragraph which replaces the original paragraph at page 5, lines 7 through 22:

The present invention provides novel means for determining the presence of HIV infection in body fluids through the use of a monoclonal antibody characterized by its specificity for an epitope on HIV I gp41 formed by a first sequence of amino acids Ile-His-Ser-Leu-Ile-Glu-Glu-Ser-Gln-Asn-Gln-Gln-Glu-Lys-Asn-Glu-Gln-Glu-Leu-Leu-Glu-Leu-Asp-Lys (SEQ ID NO:1) with at least one flanking amino acid sequence of at least 5 amino acids in length either 3'to the carboxy terminus or 5' to the amino terminus of the first sequence, with the flanking sequence having an amino acid sequence substantially corresponding to that found on native HIV I gp41 adjacent said first sequence. In a preferred embodiment of the present invention, the monoclonal antibody ("5-21-3") is described, which is useful as a test reagent in diagnostic assays. In presently preferred forms, body fluid samples from patients are analyzed by immunoassay techniques such as radioimmunoassays, fluorescent immunoassays, or enzyme-linked immunosorbent assays in either direct or competitive formats.

Marked up version of the paragraph which replaces the original paragraph at page 23, lines 23 through 26:

1) Synthesis of the peptide corresponding to gp41 amino acids 121-154 (SEQ ID NO:2).

NH_2-Asp-Arg-Glu-Ile-Asn-Asn-Tyr-Thr-Ser-Leu-Ile-His-Ser-Leu-Ile-Glu-Glu-Ser-Gln-Asn-Gln-Gln-Glu-Lys-Asn-Glu-Gln-Glu-Leu-Leu-Glu-Leu-Asp-Lys-COOH

Marked up version of the paragraph which replaces the original paragraph at page 24, starting at line 28 and continuing through page 25, line 11:

The polypeptide was purified by reversed-phase HPLC on C_4 columns, employing gradients of 0.1% TFA/water (A) and 100% acetonitrile (B) as the solvent systems at a flow rate

of 1 ml/min for the analytical column (Vydac-214-TP54, Vydac Separation Group, Hesperia, California) or 3 ml/min for the semi-preparative one (Vydac-214-TP510).
The gradient used was:

28% B	1min	28%B	20min	47%B	1min	28%B

The polypeptide elution from the HPLC column was monitored at 225 nm and 280 nm. The composition of the polypeptide was confirmed by hydrolysis in 6 N hydrochloric acid (HC1)/0.3% phenol at 150^{0}C for 2 hr in vacuo, and subsequently analyzed on a Beckman 6300 amino acid analyzer with a SICA 7000 A integration.
2) Synthesis of the peptide corresponding to gp41 amino acids 126-162 (SEQ ID NO:3).

NH_2-Tyr-Asn-Tyr-Thr-Ser-Leu-Ile-His-Ser-Leu-Ile-Glu-Glu-Ser-Gln-Asn-Gln-Gln-Glu-Lys-Asn-Glu-Gln-Glu-Leu-Leu-Glu-Leu-Asp-Lys-Trp-Ala-Asn-Leu-Trp-Asn-Trp-Leu-COOH

Marked up version of the paragraph which replaces the original paragraph at page 25, beginning at line 11 and continuing through page 26, line 3:

This sequence of the peptide was assembled on the solid support by essentially the same procedure described above. The amino acid tryptophan was protected by the formyl (CHO) group. Double coupling protocols were used for amino acids underlined in the sequence shown above. The desired peptide was deprotected and cleaved off as described for the first peptide except that the peptide-resin was treated with a mixture of 8.5 ml HF, 1.0 ml of p-cresol and 0.5 ml ethanedithiol. The cleaved peptide was extracted using 15% and 40% aqueous acetic acid. The crude peptide so obtained was analyzed and purified on a C_4 reversed-phase column as described above except the gradient used was:

35%B	1 min	35%B linear	20 min	70%B	2 min linear	35%B

3) Synthesis of peptide corresponding to gp41 amino acids 131-154 (SEQ ID NO:1).

NH_2-Ile-His-Ser-Leu-Ile-Glu-Glu-Ser-Gln-Asn-Gln-Gln-Glu-Lys-Asn-Glu-Gln-Glu-Leu-Leu-Glu-Leu-Asp-Lys-COOH

Marked up version of the paragraph which replaces the original paragraph at page 26, lines 4 through 15:

This peptide was assembled, cleaved, and purified as described for the first peptide, except that the following gradient was used for analysis and purification:

15%B	1 min	15%B	20 min linear	40%B	2 min	40%B	2 min linear	15%B

4) Synthesis of peptide corresponding to gp41 amino acids 67-154 (SEQ ID NO:4).
NH_2-Ala-Arg-Ile-Leu-Ala-Val-Glu-Arg-Tyr-Leu-Lys-Asp-Gln-Gln-Leu-Leu-Gly-Ile-Trp-Gly-Cys-Ser-Gly-Lys-Leu-Ile-Cys-Thr-Thr-Ala-Val-Pro-Trp-Asn-Ala-Ser-Trp-Ser-Asn-Lys-Ser-Leu-Glu-Gln-Ile-Trp-Asn-Asn-Met-Thr-Trp-Met-Glu-Trp-Asp-Arg-Glu-Ile-Asn-Asn-Tyr-Thr-Ser-Leu-Ile-His-Ser-Leu-Ile-Glu-Glu-Ser-Gln-Asn-Gln-Gln-Glu-Lys-Asn-Glu-Gln-Glu-Leu-Leu-Glu-Leu-Asn-Lys-COOH

Marked up version of the paragraph which replaces the original paragraph at page 27, starting at line 19 and continuing through page 28, line 10:

The stock solution of the peptide thus obtained was reduced with 50 mM DTT at 40°C for 90 minutes. The solution was brought to room temperature, and then dialyzed in a spectrapor membrane (cutoff 6500-8000) against a 0.1 M ammonium acetate buffer, pH 8.1, for 48 hr. The buffer was changed twice. After a total of 72 hr of dialysis, the peptide solution was diluted 3-fold with 0.1 M ammonium acetate buffer, pH 8.1, and allowed to stand in air for 48 hr. A UV spectrum of this peptide solution in water showed a maxima at 276 nm with a shoulder at 289

nm. The peptide was further purified on a reversed-phase C_4 column, and the analyzed as described above, using the following gradient:

30%B 1 min 30%B 20 min 65%B 1 min 30%B

5) Synthesis of peptide corresponding to gp4l amino acids 58-130 (SEQ ID NO:5).

NH_2-Thr-Val-Trp-Gly-Ile-Lys-Glu-Leu-Gln-Ala-Arg-Ile-Leu-Ala-Val-Glu-Arg-Tyr-Leu-Lys-Asp-Gln-Gln-Leu-Leu-Gly-Ile-Trp-Gly-Cys-Ser-Gly-Lys-Leu-Ile-Cys-Thr-Thr-Ala-Val-Pro-Trp-Asn-Ala-Ser-Trp-Ser-Asn-Lys-Ser-Leu-Glu-Gln-Ile-Trp-Asn-Asn-Met-Thr-Trp-Met-Glu-Trp-Asp-Arg-Glu-Ile-Asn-Asn-Tyr-Thr-Ser-Leu-COOH

6) Synthesis of peptide corresponding to gp4l amino acids 131-175 (SEQ ID NO:6).

NH_2-Ile-His-Ser-Leu-Ile-Glu-Glu-Ser-Gln-Asn-Gln-Gln-Glu-Lys-Asn-Glu-Gln-Glu-Leu-Leu-Glu-Leu-Asp-Lys-Trp-Ala-Asn-Leu-Trp-Asn-Trp-Leu-Asn-Ile-Thr-Asn-Trp-Leu-Trp-Tyr-Ile-Lys-Leu-Phe-Ile-COOH